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(54) Ablation catheter.

(57) An ablation catheter is provided with an elongated member or shaft and a plurality of helically-shaped cutting wires attached to the shaft to form a cutting basket. Each of the cutting wires has a section formed as a circumferentially subscribing arc and together the wires present a circumferential cutting area of an essentially cylindrical configuration. Obstructing matter on the inner surface of a vessel cavity, such as a blood vessel or the like, is separated from the surface as the catheter is moved through the vessel. The catheter may be inserted in a vessel in a standard fashion using a wire guide which extends through a longitudinal passageway in the shaft and a hub interconnecting the basket wire. The shaft and basket together may be contained in an outer sheath to facilitate insertion. The outer sheath with the basket in a collapsed state in the outer sheath may be readily moved past an obstruction, and the sheath withdrawn to allow the basket to expand and come in contact with the interior surface of the vessel cavity. The proximal ends of the cutting wires extend from the shaft through a vibratory transducer, and the distal ends are connected together by a hub. Electrical current is applied to electrical terminals connected to the cutting wires at the proximal end of the shaft to heat the wires to facilitate separating obstructing matter from a vessel surface. Futhermore, the vibration transducer vibrates the cutting wires to further aid in separating plaque and obstructions from soft tissue such as the intima layer of the wall of a blood vessel.

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The invention relates to ablation catheters for removing tissue and/or obstructions in body cavities such as blood or other vessels, ducts, or cavities of a body.

Opening of constricted blood vessels has been a problem for many years. Rigid dilator devices, balloon dilators, or heated balloon dilators have been used.

U.S. Patent No. 4,709,698 discloses a heatable catheter, and U.S. Patent No. 4,890,611 discloses a catheter with a shearing member.

According to the present invention there is provided a catheter as defined in claim 1.

The catheter is designed to separate an obstruction from the wall of a cavity such as a blood vessel by means of an ablation catheter provided with at least one arcuately shaped cutting wire circumscribing the interior wall of the vessel. The cutting edges or edge are intended to contact the vessel wall, and movement of the catheter in the vessel in the area of an offending obstruction causes the matter forming the obstruction to be separated from the interior wall of the vessel. The part of each wire between discontinuities, or adjacent to one discontinuity is substantially helical and is substantially transverse to the longitudinal axis of the shaft. The wires form an essentially cylindrical configuration for engaging the circumference of the inner vessel wall.

Brief description of the drawings

FIG.1 is a fragmentary perspective view of an ablation catheter, incorporating an embodiment of the invention;

FIG.2 is a side elevation of the device of FIG.1;

FIG.3 is a partial fragmentary cross section view along line 3-3 of FIG.2;

FIGs.4 through 6 are cross-sectional views of a blood vessel with the device in various configurations;

FIG.7 is a fragmentary cross-sectional view showing various co-operating parts of a catheter in accordance with an embodiment;

FIG.8 is a fragmentary cross-sectional view of an alternative embodiment of the invention; and

FIG.9 is a schematic representation showing various electrical connections.

In FIG.1, the catheter 100 comprises an elongated member or shaft 110 for insertion into a human body cavity such as a blood or other vessel, duct or cavity. The shaft is provided, at its distal end, with four helically-shaped, flexible wires 104 forming a wire cage or basket 150. Each of the wires 104 comprises an arcuate curved section 105 formed as a circumferentially subscribing arc and a proximal end extending from the distal end of elongated member shaft 110 and ultrasound transducer 101. The wires 104 further each have a distal end terminating means such as a hub 103. The catheter may be percutaneously inserted in a vessel, such as a blood vessel, in a standard fashion by the well-known method of first inserting a wire guide in the vessel and subsequently inserting the catheter over the wire guide. FIG.1 shows wire guide 102 extending through central passageway 107 that extends longitudinally through hub 103 and through longitudinal passageway 111 in shaft 110. Wire guide 102 can alternatively be fixed relative to hub 103 to allow guide 102 to control movement of the wires. After the wire guide has been inserted in a blood vessel, the catheter may be inserted over the wire guide and into the vessel. The flexible cutting wires 104 will generally be in contact with the interior wall, lining, or surface of the vessel as the catheter is moved in the vessel. When an obstruction in the vessel is reached, the end portion of the catheter with the wires 104 is preferably moved past the obstruction and then withdrawn. In the process of withdrawal, the arcuate curved sections 105 of the wires 104 contact the wall of the vessel to separate the obstructing matter from the wall of the blood vessel. The wire basket 150 is provided with a particulate collecting net formed by a plurality of threads 112 such as suture material attached with; for example, a medical grade adhesive to the wires 104 at a number of spaced apart positions. The net formed by the several threads 112 captures the matter separated from the vessel wall by the wire basket as the catheter is moved through a blood vessel or the like.

Each of the wires 104 comprises a first curved or straight section 123 extending from the distal end of shaft 110 to a discontinuity such as a corner or kink 125. From the discontinuity, the wire extends laterally outwardly and preferably longitudinally at an angle determined to form an arcuately shaped section 105 designed to engage the internal surface of the body cavity when in the operative condition. The wire section 105 preferably subtends an angle of approximately 90° or less to the section 104 to form the discontinuity, although it will be appreciated that angles significantly less than 90° will suffice. It is required that the section 105 conforms to the internal dimension of the cavity and the angle is selected to meet that requirement. Each wire can gradually extend longitudinally from section 105 to the distal end thereof, or can preferably continue as a continuously contacting section 105 until a second discontinuity, such as 121, of the wire, from which the wire then progresses in a non-contacting section 120 to the distal end of each wire. The continuously contacting section of each wire is substantially helical and subtends an angle to the longitudinal axis of the shaft which is substantially or significantly greater than the angle subtended by the sections 120, 123. The wire 123 at discontinuity 125 is bent to give a more lateral component and/or outward component to the direction of the wire. The bend can extend from a small angle (such as 5°) to an angle greater than 90° but

preferably is approximately 90° or less.

Section 120 facilitates entry of the catheter in a blood vessel and past a constricting obstruction. The approximately right angle corners 121 and 125 are further illustrated in the side elevation of FIG.2. The flexible wires 104 may, for example, be stainless steel wires having a diameter in the range of 0.006" to 0.01".

Alternatively, a superelastic metallic alloy wire may be used having a superelastic state above its transformation temperature, such as Nitinol, a well-known nickel-titanium alloy. Tantalum may also be used or included for greater radiopacity.

The curved sections 105 of the four wires are formed in an overlapping arrangement which is demonstrated in Fig.3, which is a cross section along line 3-3 of FIG.2. For the sake of clarity, only two of the wires, labelled 131 and 132 in FIG.3, are shown. Wire 131 originates at point 133 on the end cap transducer 101, and wire 132 originates at point 135 on end cap transducer 101. Wire 131 overlaps wire 132 in a quarter of the circumference of the wire basket 150, as shown at 137. In a similar manner, wire 132 overlaps a portion of an adjacent wire (not shown in FIG.3) originating from point 134. The wire originating from point 134 would similarly overlap a wire originating from point 136 on end cap transducer 101. In this manner, the wire basket presents a circumferentially extending cutting surface to the interior wall of a blood vessel or the like.

The degree of overlapping is designed to permit sufficient expansion of the cage so that the wires have continuous contact with the internal surface of the body cavity. When expanded fully, overlapping may not be required, but is preferred.

To facilitate insertion of the catheter 100 in an obstructed vessel, the catheter may be provided with an outer sheath or guiding catheter for containing the shaft 110 and particularly for maintaining wire basket 150 in a compressed configuration. FIG.4 depicts the shaft 110 and wire basket 150 contained within sheath 140 and disposed within a vessel 211 having an inner wall 210 and constricting obstructions 200. In preparation for insertion of the catheter, a wire guide 102 is inserted in the blood vessel or the like using a well-known radiological procedure. The shaft 110 and wire basket 150 are inserted over the wire guide while positioned within the outer sheath 140. Preferably, the sheath is extended beyond a constricted area such as that formed by obstructions 200 on the inner wall 210 of vessel 211. The sheath 140 is withdrawn to allow wire basket 150 to assume an expanded configuration as depicted in FIG.5. The shaft 110 may then be withdrawn bringing the cutting wire sections 105 in contact with the obstructions 200 and causing the matter forming the obstructions to be separated from the vessel wall, as depicted in FIG.6. As the matter forming the obstructions is cut away from the wall, it is collected in the particulate collecting net formed by the several threads 112 extending between the cutting wires 104. In this manner, the obstructing deposit is separated from the wall of the vessel and the particulate is removed from the vessel as the catheter is withdrawn. The threads which form the net may be suture or other suitably strong but flexible filament which will not interfere with the collapsing of the wire basket 150 when it is drawn into the sheath 140. It is also contemplated that the expanded basket may be pushed forward to separate the obstructions from the vessel wall.

FIG.7 discloses a further enhancement to the catheter 100 which provides control over the degree of lateral expansion of the wire basket 150. An adjustment rod 160 extends longitudinally through shaft 110 as shown in FIG.7. The adjustment rod 160 has a distal end attached to hub 103 and is provided at its proximal end with a cylindrically-shaped handle 174, including a shoulder 175. The rod 160 slideably engages a longitudinally-extending passageway 162 in shaft 110. Movement of the rod 160 in a direction such that the handle 174 is moved away from the shaft 110, causes the hub 103 to be moved toward shaft 110 and causes the cutting wires 104 to extend laterally, thereby increasing the cross-sectional area of the basket 150. Conversely, as the rod 160 is moved in a direction wherein the handle 174 is moved toward the shaft 110, the hub 103 is moved away from the shaft 110 causing the cutting wires 104 to be expanded longitudinally, thereby reducing the cross-sectional area of the basket 150. It will be readily apparent from the perspective view of FIG.1 that the circumference of the basket 150 will be expanded as hub 103 is moved in the direction of the shaft 110 and that its circumference will be reduced as the hub 103 is moved away from the shaft 110. The adjustment rod 160 is provided with graduation markings 172 which correspond to degrees of expansion of the basket 150 and may be readily used by a physician to expand the basket by a precise amount while the basket is disposed internal to a vessel. A sliding lock ring 166 engages the tapered proximal end portion 168 of shaft 110. As the lock ring 166 is moved in the direction of the main portion of the shaft 110, the end portion 168 of shaft 110 will be compressed to maintain the adjustment rod 160 at a desired position. A wire guide 102 is shown disposed in a longitudinally extending passageway 170 of the adjustment rod 160.

FIG.8 is an alternative embodiment of a net for collecting particulate 200 resulting from the cutting action of the wire basket 150. The net 202 may be formed of a gauze material or nylon netting and is attached to the cutting wires 104 in the proximity of the near 90° corners 121. The net 202 extends longitudinally beyond the hub 103 at the distal end of the catheter 100. The net 202 is provided with a central opening 201 at its distal end to allow for passage of the wire

guide 102.

To enhance the cutting action of the cutting wires 104 and to melt obstructing material such as cholesterol or plaque or ablate soft tissue such as the mucosa of a gallbladder, the cutting wires may be heated by means of the application of electrical current to the cutting wires. This is accomplished by interconnecting the cutting wires 104 within the hub 103, as depicted in schematic of FIG.9. The cutting wires 104 are shown connected in pairs by means of interconnected electrical conductors 212. Instead of using separate conductors, the wires may be joined for electrical contact in any suitable manner. Electrical current may be applied to the cutting wires 104 in shaft 110 by electrically conducting terminals 208 as generally depicted in FIG.9. Cutting wires 104 are connected by means of electrical connector 213 to a switch unit 204 to which the appropriate current for such heating purposes is supplied from cable 206. The amount of electrical power and the frequency desired for the cutting operation is a matter of choice and will depend upon the requirements for the particular surgery procedure to be performed. The switch unit 204 may be any well-known switch configuration in which input current is supplied to one of conductor pairs 212. The return current path includes the other one of conductor pairs 212. Accordingly, in the configuration of this illustrative embodiment wherein two interconnected pairs of cutting wires are employed, one of the conductor pairs 212 will be input current conductors, and the other one of the conductor pairs will be return current conductors. Switch 204 is provided with a push button switch 205 which is operative to connect the input current of the desired magnitude and frequency from cable 206 to one of the conductor pairs 212 while the remaining conductor pair is connected to a return current lead of cable 206.

The cutting action of the cutting wires 104 may be further enhanced by vibratory motion. An ultrasonic transducer 203 in end cap transducer 101 is attached to the cutting wires 104 to impart ultrasonic vibration to the cutting wires. The vibrator may be any one of a number of well-known such devices and may be conveniently embedded within end cap transducer 101 of the shaft 110. Power for the transducer is provided by means of a pair of wires 209 connected to switch unit 204 and which may be interconnected with supply wires, likewise provided via cable 206 to switch 204, by operation of push button switch 207. The push button switch is preferably located near the distal end of the shaft 110 to conveniently allow the surgeon to selectively apply heat or vibratory motion to the cutting wires 104.

The ablation catheter may be inserted in the fundus of a gallbladder via a retrograde route through the common and cystic ducts to ablate the mucosa of a gallbladder. The wires of the expandable basket would enlarge to engage the mucosal layer and apply radiofrequency current to heat and coagulate the mucosal layer. The ablation of the mucosal layer is known to prevent the reformation of gallbladder stones. Also contemplated is the use of the device for removing urinary obstructions in the urethra, especially in the prostatic urethra in men. Also it is contemplated that polyps in the intestinal tract can be removed with this device.

Claims

1. An ablation catheter comprising an elongated member (110), at least one wire (104) extending at the proximal end from the distal end of the said member, and at the distal end to an interconnection arrangement (103), the wire having an arcuately shaped section (105) forming part of a wire cage which when expanded and moved, serves to contact and remove tissue from the internal surface of a body cavity, characterised in that the wire has at least one discontinuity (125) for imparting a lateral component to the direction of the wire (105) whereby peripheral contact of the wire with the said internal surface is increased.

2. A catheter according to claim 1, characterised in that there are a plurality of wires each disposed in the manner of the first mentioned wire.

3. A catheter according to claim 1 or 2, characterised in that each wire has a second discontinuity with the part of the wire between the said one and second discontinuities in contact with the said internal surface.

4. A catheter according to claim 3, characterised in that the said part of the wire adjacent to the respective discontinuity subtends an angle which directs the said part to form a circumferentially subscribing helical arc, each such helical arc being in overlapping relationship with a helical arc from an adjacent wire in order to permit expansion of the cage and the maintenance of the said peripheral contact.

5. A catheter according to claim 4, characterised in that the said angle is in the region of 90°, with each said part forming a helical arrangement substantially transverse to the longitudinal axis of the said member.

6. A catheter according to any one preceding claim, characterised in that means (160,166) are provided for controlling the expansion of the cage, said means being mechanically coupled to the shaft and the interconnection arrangement, whereby the distance between the distal end of

the shaft and the interconnection arrangement can be controllably varied.

7. A catheter according to any one preceding claim, characterised in that the shaft includes a hollow passageway (111) therein for insertion of a wire guide (102) and in that the wire guide can extend through or be fixed to the interconnection arrangement.

8. A catheter according to any one preceding claim, characterised in that each wire is electrically conductive and connected so that it can be heated to facilitate removal of said tissue.

9. A catheter according to any one preceding claim, characterised in that vibratory means (101) is provided in contact with each wire (104) to impart vibratory motion thereto.

10. A catheter according to any one preceding claim, further characterised by an outer sheath (140) having a longitudinal passageway therethrough for containing the shaft and the wire cage during insertion of the latter into the cavity.

11. A catheter according to any one preceding claim as appendant to claim 2, characterised in that a collapsible net (202) is attached to the cage to collect tissue when removed from the cavity by the wires of the cage.

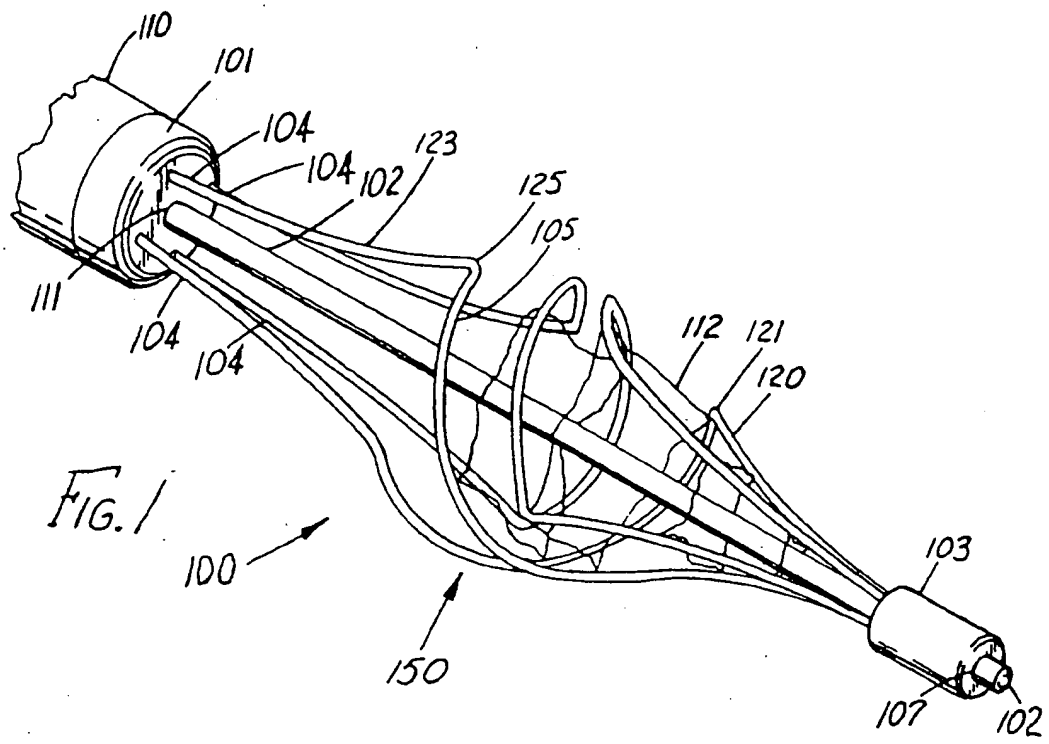

FIG. 1

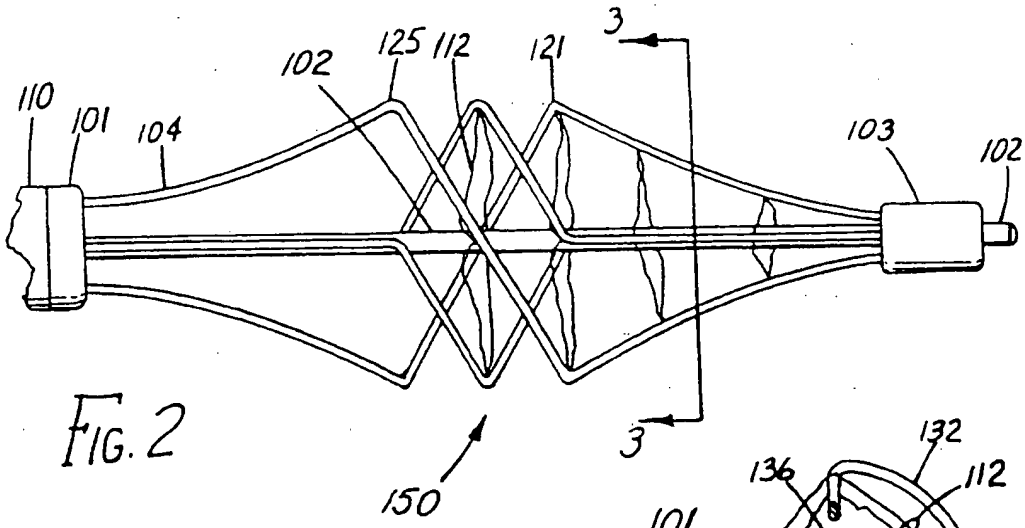

FIG. 2

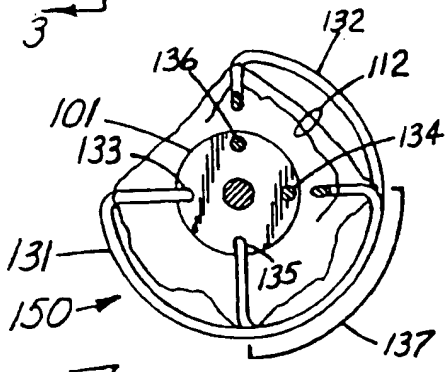

FIG. 3

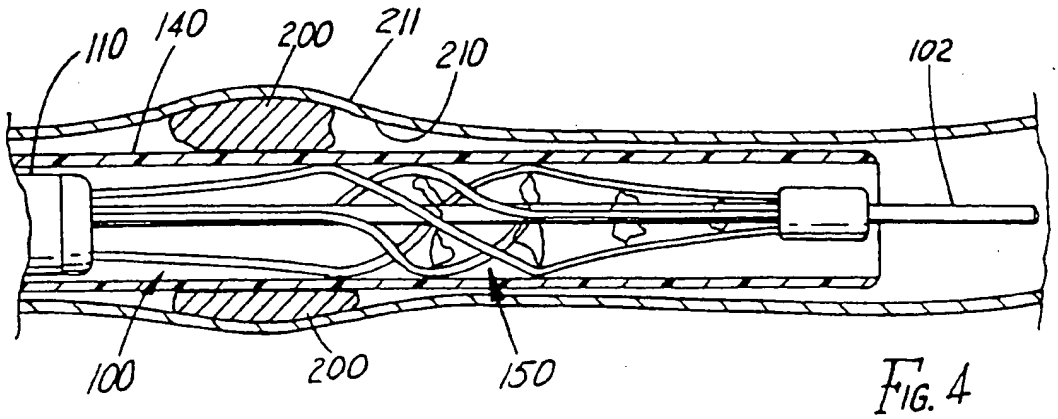

FIG. 4

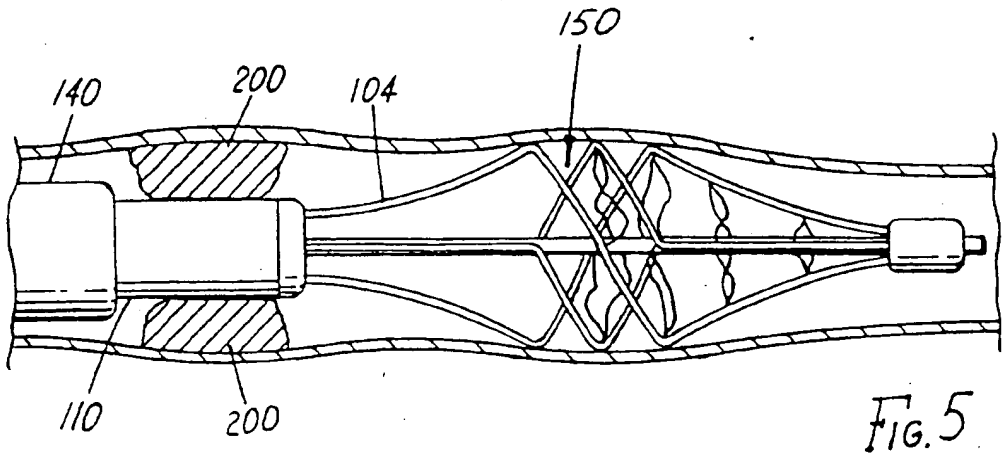

FIG. 5

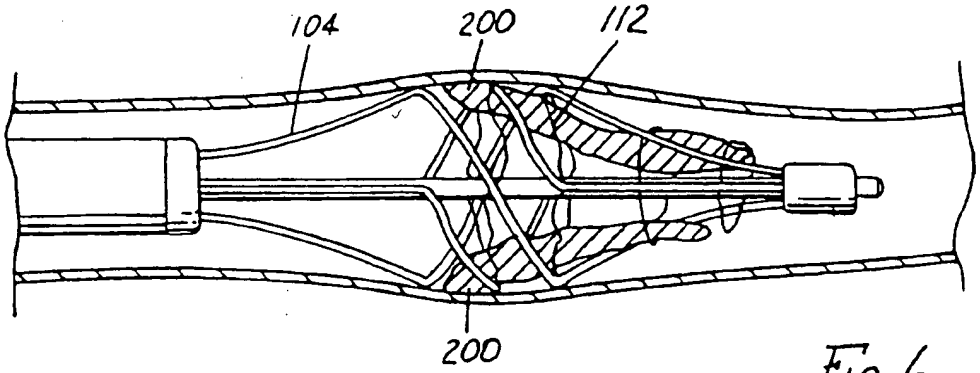

FIG. 6

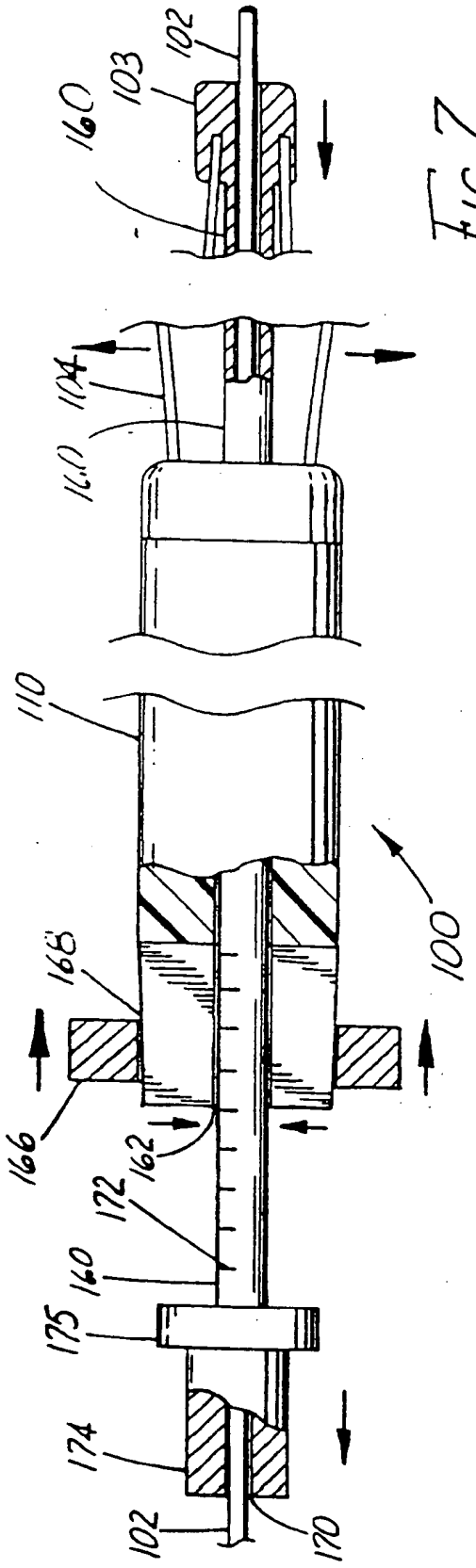
160
103
102
104
110
100
168
166
162
172
160
175
174
102
170

FIG. 7

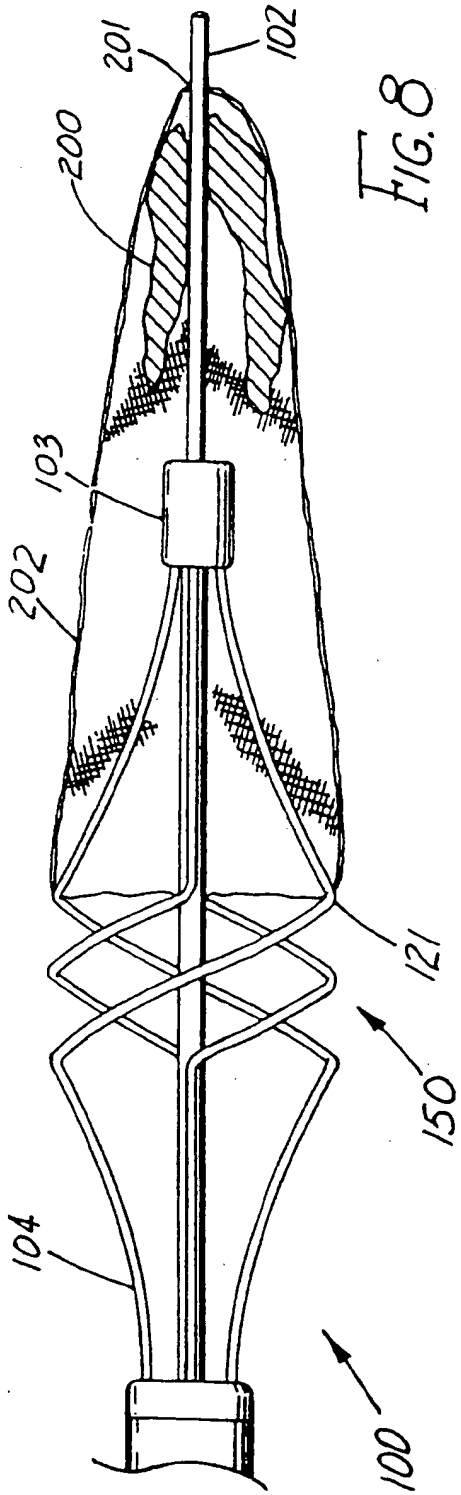
201
102
200
103
202
121
150
104
100

FIG. 8

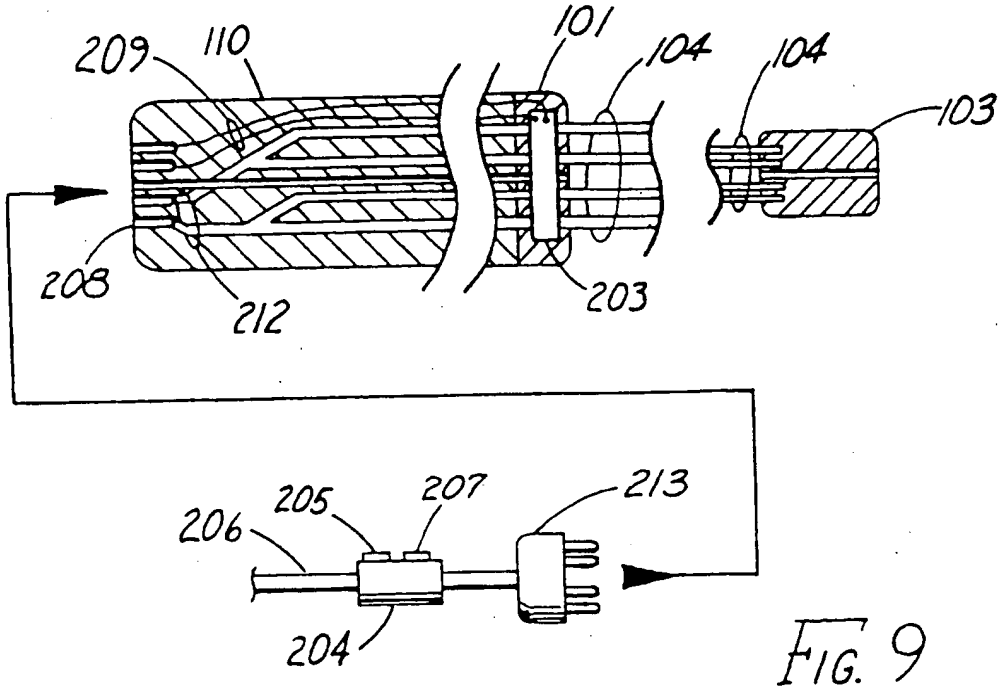

FIG. 9